K072827

# 510(k) SUMMARY

**Contact Information:** **Andre Hsiung**
Technical Projects Manager
Remel Inc.
Thermo Fisher Scientific
12076 Santa Fe Drive
Lenexa, KS 66215
Phone: (913) 895-4264
Fax: (913) 895-4264
email: andre.hsiung@thermofisher.com



**Date Prepared:** July 14, 2007

**Device Trade Name:** RPMI 1640 Agar w/ MOPS and 2% Glucose

**Predicate Device:** Mueller Hinton Agar w/ 2% NaCl

**Device Classification:** 21 CFR 866.1700; Culture medium for antimicrobial susceptibility tests

**Intended Use:** Remel RPMI 1640 Agar w/ MOPS and 2% Glucose is a solid medium recommended for use with antibiotic gradient-based systems for quantitative determination of susceptibility to antifungal agents when testing *Candida* spp. directly from colonies grown on nonselective media.

**Device Description:** RPMI-1640 was developed by Moore et al. at Roswell Park Memorial Institute. The formulation is based on the RPMI-1630 series of media utilizing a bicarbonate buffering system and alterations in the amounts of amino acids and vitamins. RPMI-1640 medium has demonstrated wide applicability in cell culture and also as the reference method for antifungal broth microdilution recommended by Clinical Laboratory Standards Institute (CLSI). When properly supplemented with MOPS, glucose, and agar RPMI-1640 has demonstrated accuracy for use with gradient-based systems with results comparable to that obtained with the CLSI reference method for testing *Candida* spp. against antifungal agents.

The gradient method is based on a combination of the concepts of both dilution and diffusion tests, but differs from conventional disk methods by the use of a preformed, stable antibiotic gradient strip. When the strip is applied to the inoculated agar plate, there is an immediate release of the

antibiotic into the agar matrix. A continuous and exponential gradient of antibiotic concentration is created beneath the carrier. After incubation a symmetrical inhibition ellipse centered along the carrier is seen. The zone edge intersects the strip at the minimum inhibitory concentration (MIC) value given in µg/ml. For antifungal testing, due to trailing effect, MICs should be read at approximately 90% inhibition of growth, ignoring faint hazes and minute colonies for flucytosine and 80% inhibition for fluconazole and itraconazole.

**Device Comparison:**

| Characteristic | Device | Predicate |
|---|---|---|
| Intended Use | Remel's RPMI 1640 Agar w/ MOPS and 2% Glucose is a solid medium recommended for use with antibiotic gradient-based systems for quantitative determination of susceptibility to antifungal agents when testing *Candida* spp. directly from colonies grown on nonselective media. | Remel's Mueller Hinton Agar w/ 2% NaCl is a solid medium recommended for use with antibiotic gradient-based systems for quantitative determination of susceptibility to methicillin and oxacillin when testing staphylococci directly from colonies grown on nonselective media. |
| Incubation | 35° C | 35° C |
| Inoculation | *Candida* spp. | *Staphylococcus* spp. |
| Technology | To be used with predefined and preformed antifungal gradient on a plastic strip. Single antifungal agent per strip. | To be used with predefined and preformed oxacillin gradient on a plastic strip |
| Interpretation | MICs should be read at approximately 90% inhibition of growth ignoring faint hazes and minute colonies for Flucytosine and 80% inhibition for Fluconazole and Itraconazole. | MIC is read at the end point where there is complete inhibition |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 6 2007

Mr. Andre Hsiung
Technical Project Manager
Remel Inc.
Thermo Fisher Scientific
12076 Santa Fe Drive
Lenexa, KS 66215

Re: k072827
Trade/Device Name: RPMI 1640Agar w/ MOPS and 2% Glucose
Regulation Number: 21 CFR 866.1700
Regulation Name: Culture medium for antimicrobial susceptibility test
Regulatory Class: Class II
Product Code: MJE
Dated: October 1, 2007
Received: October 3, 2007

Dear Mr. Hsiung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): k072827

Device Name: **RPMI 1640 Agar w/ MOPS and 2% Glucose**

Indications For Use: **Remel RPMI 1640 Agar w/ MOPS and 2% Glucose is a plated medium recommended for use with antibiotic gradient-based systems for quantitative determination of susceptibility to antifungal agents when testing *Candida* spp. directly from colonies grown on nonselective media.**

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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